UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,442	01/21/2004	John A. Krueger	SPEC-6203	5176

7590 04/11/2006

Attn: Kim Luna
ALLEGIANCE CORPORATION
MPKB-1A
1430 Waukegan Road
McGaw Park, IL 60085-6787

EXAMINER	
JOHNSON, JERROLD D	
ART UNIT	**PAPER NUMBER**
3728	

DATE MAILED: 04/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/762,442	KRUEGER ET AL.	
	Examiner	Art Unit	
	Jerrold Johnson	3728	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 January 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) *21-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

This application contains claims drawn to an invention nonelected with traverse. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicant's election with traverse of the restriction requirement is acknowledged. The traversal is on the ground(s) that the search of the method claims is commensurate with that of the product claims. This is not found persuasive because the method claims are additionally drawn to agitating, which is classified in class 366. The search for the product does not encompass class 366.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 1,7,8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chan US 6,516,977 in view of Howson et al. US 4,834,152 and Ronk US 5,951,160.

Chan discloses a surgical cement preparation system for combining a liquid ingredient together with at least one powder ingredient comprising:

a needle and syringe assembly 275, wherein said needle is structured to couple to said syringe and comprises a closed distal tip and at least one lateral opening located at the distal end of said needle col. 6 lines 12-15 which describes a cannula of the type commonly used to inflate balls, which are known to comprise lateral openings; and

a mixing vial 10, said mixing vial comprising a removable cap 270 structured to sealably close the end of said mixing vial and said cap further comprising a second opening therethrough and a second cap 80 structured to sealably close said second opening.

Chan inferentially discloses the lateral openings in the distal end of the needle by way of his example, but does not explicitly disclose this structure.

Fogdog sports provides extrinsic evidence (i.e. this reference is for evidence only, it is not applied against the claim) that inflation needles commonly include lateral openings.

Ronk explicitly discloses the needle structure with lateral openings for the passage of a liquid surgical cement component into a powdered component. The benefits of this teaching are known to be better distribution of the liquid within the

powder, and for this reason it would have been obvious to one of ordinary skill in the art to provide Chan with this explicit teaching.

Additionally, with respect to the limitations drawn to the removable cap, Chan discloses a cap 80 over a second opening in the removable cap 270. Chan, however, does not explicitly set forth that the cap is removable.

Firstly, merely making something separable does not typically confer patenability. See MPEP 2144.04 V. C. In this situation, the desirability of making the cap 80 separable and thus removable would be that were the cap 80 damaged in use, the cap 80 would be replaceable.

Secondly, a removable cap is considered an art recognized equivalent to the cap 80 of Chan. A removable cap would provide the same function (the admission of a syringe) in substantially the same way (through an opening) to produce the same result (sealing the opening beneath the cap to minimize vapor release). Accordingly, a removable cap would be an equivalent structure to the cap 80 to those of ordinary skill in this art. For that reason, it would have been obvious to one of ordinary skill in the art to have used a removable cap in place of the cap 80 within the invention of Chan.

Thirdly, Howson explicitly sets forth a cap 45 on a second opening in a removable cap. The opening that is closed by the cap 45 is used for the insertion of a syringe. Accordingly, from this teaching of Howson, it would also have been obvious to one of ordinary skill in the art to provide removable cap for the second opening in the cap of Chan. The cap as taught by Howson would provide the same benefits as the cap 80 currently used in Chan, i.e. minimize fumes, allow a vacuum to be created in the vial,

and permit a syringe needle to extend into the vial therethrough. However, a removable cap would not be subject to damage or deterioration from use, as would the cap 80 currently used by Chan which could be damaged when a needle is passed through it.

And fourthly, Howson in a second embodiment Figs. 5,6 and 14 discloses how a removable cap 68 is used over the opening in 72 so as to maintain sterility (see col. 7, lines 28-37. Accordingly, Howson teaches that it would have been obvious to one of ordinary skill in the art to include a removable cap over the cap 80 of Chan so as to maintain sterility.

Accordingly, with respect to Applicants arguments, within the teachings of Chan and Howson there are at least four reasonable rationales that the removable cap set forth in the claim is obvious over these two references.

Regarding Applicants arguments about the use of a sports ball inflation needle, Applicant apparently did not read Chan col. 6, lines 12-20. The Examiner has not pulled sports ball inflation needles from mid air. Chan discloses the use of this very structure to describe his needle. Ronk merely provides extrinsic evidence to support the Examiner assertion of what Chan himself describes. Howson supports this analysis. Howson also shows a needle having lateral openings (such as are described by Ronk), with the needle penetrating through a membrane (just like Chan). See the front page drawing figure of Howson.

Accordingly, neither of the concepts set forth in claim 1 (the needle with lateral openings, or the removable cap) confer patentable subject matter over Chan, Howson and Ronk.

Re claim 7, Howson discloses a plurality of lateral openings.

Re claim 8, the syringe of Chan includes a plunger (piston 300).

Re claim 10, the second opening is dimensioned to accommodate insertion of the needle.

2. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chan US 6,516,977 in view of Howson et al. US 4,834,152 and Ronk US 5,951,160, as applied above, and further in view of Miller et al. US 6,783,515.

Re claim 9, Miller discloses polypropylene in a surgical cement applicator in col. 9, line 52. Polypropylene is well known in this art for its compatibility with the chemicals in PMMA surgical cement.

Accordingly, it would have been obvious to one of ordinary skill in the art to use polypropylene in the syringe components.

3. Claims 2,5,6,11-13 and 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chan US 6,516,977 in view of Howson et al. US 4,834,152 and Ronk US 5,951,160, as applied above, and further in view of Bonitati et al. US 5,586,821, Harrod US 4,526,303, Porter US 3,211,195 and Hughes et al. US 6,364,519.

Again, Chan US 6,516,977 in view of Howson et al. US 4,834,152 and Ronk US 5,951,160 discloses the needle and syringe and the mixing vial as claimed. Chan further discloses the vial 210 dimensioned to accommodate the liquid component of the cement.

Neither Chan nor Howson or Ronk disclose a funnel or spatula. Chan, does however, disclose in col. 4, lines 44-46 mixing the cement in his mixing vial, and then transferring the mixed cement into a applicator (not shown). He does not disclose the use of a funnel in this process.

Funnels are well known in this art for the administering of the cement ingredients into a mixing chamber, for the administering of mixed cement into the chamber of an applicator, and for the administering of ingredients into a mixing chamber when the mixing chamber is also the cement chamber of an applicator.

Bonitati et al. US 5,586,821 discloses a kit including a funnel 90 for administering of the cement ingredients into a mixing chamber.

Harrod US 4,526,303 discloses a funnel 29 for the administering of mixed cement into the chamber of an applicator. Solomon, for the purposes of extrinsic evidence, discloses a funnel 18 for administering the ingredients into a mixing chamber when the mixing chamber is also the cement chamber of an applicator.

It is recognized that neither Bonitati nor Harrod disclose the use of a single funnel for both purposes.

Porter US 3,211,195 discloses how a single funnel 1 is designed to be compatible with a variety of container opening sizes.

Accordingly, as it is known to use a funnel for administering cement ingredients into a mixing chamber (Bonitati), and as it is known for administering mixed cement into the chamber of an applicator (Harrod), and as it is further known to use a single funnel having a structure to mate securely with different sized containers, it would have been

obvious to one of ordinary skill in the art to have provided a single funnel such as that disclosed by Porter to the invention of Chan to facilitate the administering of the cement ingredients into the mixing vial 10 and then to facilitate the administering of the mixed cement into an applicator.

With respect to Applicants arguments, Applicant has argued that what distinguishes his invention over that taught by Bonitati, Harrod and Porter is that his funnel securely attaches to more than one container. Porter clearly discloses this concept. Additionally, the limitation "securely attach" to which Applicant relies in his arguments is not set forth in the claims, but if it were, Porter clearly discloses a funnel inherently capable of achieving this result.

Regarding the first vial dimensioned to completely accommodate a liquid ingredient container (the liquid monomer) within, Hughes et al. US 6,364,519 discloses providing a first vial 10 dimensioned to completely accommodate a liquid ingredient container (the liquid monomer).

Accordingly, it would further have been obvious to one of ordinary skill in the art to provide the monomer liquid vial in a first vial so as to protect the fragile monomer vial prior to insertion into the syringe of Chan.

Re claim 5, Hughes discloses the first vial comprising a container 30 having a removable cap 18.

Although not claimed explicitly in claim 5, a container disclosing a cap which can be *reinstalled* on the container is not disclosed by Hughes, nor the other cited references, for accommodating a liquid monomer vial.

However, the Examiner takes Official Notice that providing fragile vials in containers having removable caps is common to ensure against breakage of the vials. For example, pharmacists commonly do this when supplying prescriptions of epinephrine in vial form. Accordingly, it also would have been obvious to provide the monomer vial in a container having a removable cap (like a pill container) so that the vial is properly protected in transit, it further would be obvious for this container to be compatible with monomer liquid in case the vial breaks accidentally.

Re claim 6, Hughes inherently discloses that the first vial is compatible with the liquid monomer. This is evidenced by the fact that the liquid monomer and the powder can be mixed within the first vial.

Re claims 11-13, Porter discloses this arrangement.

Re claim 16, Bonitati disclose a tray.

Re claim 17, Chan discloses a pre-filled liquid in a vial, and Bonitati discloses pre-filled liquid in a vial 12.

Re claim 18, Bonitati (14) discloses pre-filled containers with powder ingredients.

Re claim 19, Chan discloses the powdered ingredient in the mixing vial.

Re Applicants arguments that the Examiner has relied on impermissible hindsight, it is submitted that Applicant has not indicated with any specificity which teachings have been so applied. In the absence of such arguments, the Examiner cannot address this broad generalization of the Examiner's rejection.

4. Claims 3,4,14,15 and 20, are rejected under 35 U.S.C. 103(a) as being unpatentable over Chan US 6,516,977 in view of Howson et al. US 4,834,152 and Ronk US 5,951,160, as applied above, and further in view of Bonitati et al. US 5,586,821, Harrod US 4,526,303, and Porter US 3,211,195, as applied above, and further in view of Murphy US 6,273,916.

Re claim 3 and 4, the claimed ingredients of the surgical cement are disclosed within the aforementioned references, as well as within Murphy US 6,273,916. Murphy further describes the use of barium as an opacifier in col. 5 and 6. The Examiner takes Official Notice that barium sulfate, the common form of barium within PMMA surgical cement, is well known in this art and is commonly used to assist in imagery.

Accordingly, it would have been obvious to have included a barium sulfate opacifier in the surgical cement so that the cement could be imaged properly both during and after surgery.

Re claims 14 and 15, the mixing of surgical cement is known to involve the use of a spatula. Such spatulas are also known to be used when transferring the mixed cement to an applicator. Additionally, spatulas are generally well known to be used with mixed ingredients of all types when transferring the ingredients to another container, such as is commonly done while baking.

Murphy US 6,273,916 explicitly discloses a kit including a spatula 88 and 108. The spatula is of a small size that would be suitable for the intended use set forth in claim 14, as it would clearly be sufficiently small to fit within almost any funnel. Murphy discloses the structure of the spatula set forth in claim 15.

Accordingly, it would have been obvious to one of ordinary skill in the art to provide the spatula of Murphy to manually assist in any mixing that must be performed as well as to assist in the administering of the cement into the funnel while loading the cement applicator.

Re Applicant's arguments, the Examiner has not asserted that Murphy includes a funnel. Additionally, with respect to Applicant's assertion that the Examiner has appropriated teachings that only reside within in the Examiner's imagination, it is noted that Hughes US 6,364,519 and Bonitati 5,586,821 are but two of the references which support the Examiner's assertions set forth above with respect to the common use of funnels in bone cement preparation kits. Furthermore, the absence of a funnel in the system of Murphy in no way evidences that a funnel would not have been used with his system, particularly as a funnel is necessary for pouring accuracy. And, it is noted that it was (and continues to be) the Examiner's assertion that the size of the spatula of Murphy as shown in his drawings appears to be of a size that would permit its use within a funnel that would likely be used with his system.

Nevertheless, Applicant's desire to see an express teaching of a spatula sized to be used both within a funnel and a mixing vial is noted. It is noted that patents do not always disclose commonplace details such as this.

In response, Aurin et al. US 2004/0030345 in paragraph [0008] provides extrinsic evidence in support of the Examiner's factual assertions of the commonplace use of a spatula within a funnel. Clearly, such a funnel would also fit within a mixing vial. And,

clearly, a mixing vial would be likely used to mix the bone cement used in the syringe of Aurin, as that is the common manner of preparing bone cement.

Accordingly, it is submitted that the motivations for the application of the teaching that it would have been obvious to one of ordinary skill in the art to have made the spatula of Murphy of a size such that it would fit within a mixing vial and a funnel are what fall into the category of "that which is generally known in the art." Aurin supports this assertion.

Applicant's arguments directed to this rejection are noted but are not persuasive.

Re claim 20, although Chan does disclose a powdered ingredient within his mixing vial, Chan does not disclose an opacifier within his powdered ingredients. Murphy discloses the common use of opacifiers within surgical cement to permit imaging of the surgical cement.

Accordingly, it would have been obvious to have pre-filled the mixing vial of Chan with an opacifier so as to increase the speed at which the loading of the mixing vial with ingredients is performed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerrold Johnson whose telephone number is 571-272-7141. The examiner can normally be reached on 9:30 to 6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on 571-272-4562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JDJ

Mickey Yu
Supervisory Patent Examiner
Group 3700